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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/806,423

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Thomas P. Jerussi

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EXAMINER

KAROL, JODY LYNN

ART UNIT

PAPER NUMBER

1617

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/806,423	Applicant(s) JERUSSI ET AL.	
	Examiner Jody L. Karol	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/13/2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 92 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/13/2008 and 8/19/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment/Remarks filed 6/13/2008. Claims 61-63, 67-91, and 93-94 have been cancelled. Thus, claim 92 is currently under consideration/pending.

Information Disclosure Statement

1. The information disclosure statements (IDS) filed on 6/13/2008 and 8/19/2008 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered. However, references "CU" and "CT" on the 8/19/2008 IDS have not been considered because English language translations of the documents were not provided, and their relevance to the application has not been indicated.

Terminal Disclaimer

2. The terminal disclaimer filed on 6/13/2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6,911,479 has been reviewed and is accepted. The terminal disclaimer has been recorded.

WITHDRAWN REJECTIONS

3. In view of Applicant's arguments, the rejection of claim 92 on the ground of nonstatutory obvious-type double patenting as being unpatentable over claims 1,4,12, 14-16, and 61 of copending Application No. 11/091,581 is herein withdrawn.

4. The rejection of claim 92 on the ground of over on the ground of nonstatutory obvious-type double patenting as being unpatentable over claims 4 and 10-15 of U.S. Patent No. 6,911,479 B2 to Jerussi et al. is moot in view of the Terminal Disclaimer filed 6/13/2008.

MAINTAINED REJECTIONS

5. The following rejections have been maintained from the previous Office Action dated 4/2/2008:

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 92 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rudolph et al. (EP 0 639 374 A2).

Claim 92 is directed to a method of treating a patient suffering from anxiety comprising providing to a patient in need thereof an effective amount of (-)-O-desmethylvenlafaxine hydrochloride.

Rudolph et al. teaches use of 1-[2-dimethylamino)-2-4(hydroxyphenyl)ethyl]-cyclohexanol (O-desmethylvenlafaxine) or pharmaceutically acceptable salt thereof for the treatment of anxiety (see abstract, page 8, lines 47-49 and pages 8-9, claims 1-2 and 5). Rudolph et al. further teaches that use of venlafaxine analogs (i.e. O-desmethylvenlafaxine) includes racemates and the individual enantiomers (see page 3,

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lines 7-10) and that pharmaceutically acceptable salt forms include hydrochloric acids (see page 5, lines 54-57).

Rudolph et al. does not explicitly teach a method of treating anxiety with the (-) enantiomer of O-desmethylvenlafaxine.

However, as stated above, the Examiner cited prior art teaches O-desmethylvenlafaxine as a racemic mixture, placing the skilled artisan in possession of both optical isomers. Absent some difference in kind between the various isomers the skilled artisan would have seen each isomer as *prima facie* obvious (see *In re Adamson and Duffin*, 125 USPQ 233 (CCPA 1960)). The skilled artisan would have expected optical isomers to be separable and isomers so separated to exhibit physiological effects at varying levels. Possessing a compound known to contain chiral centers, places all the resultant compounds in the skilled artisan's possession. Therefore, it would follow that the instant claims recite *prima facie* obvious subject matter and are properly rejected under 35 USC 103. As admitted on the record, O-desmethylvenlafaxine is taught by the Examiner cited prior art as optically active. Thus, use of one or another optical isomer by the skilled artisan would have seen as *prima facie* obvious, absent some difference in kind between the various isomers (see *In re Adamson and Duffin*, 125 USPQ 233 (CCPA 1960)).

It is well settled patent law that optical isomers would have been expected to possess different therapeutic activities. Most biological systems are sensitive to optical isomerism, motivating the skilled artisan to expect one or another optical isomer to effect greater, or lesser physiological activity.

Thus, the invention as a whole would have been *prima facie* obvious to one skilled in the art at the time it was made.

Response to Arguments

Applicant's arguments filed 6/13/2008 have been fully considered but they are not persuasive.

Applicants allege that Office Action's basis for the rejection essentially amounts to the proposition that no claims to optical isomers are *prima facie* non-obvious over prior disclosure of a racemic mixture (see page 4, 2nd paragraph). The Examiner respectfully disagrees. As record as stated in the 4/2/2008, an optical isomer is *prima facie* obvious over the racemic mixture provided there is not a different in kind between the isomers. Thus, a different in kind between optical isomers is evidence of non-obviousness.

A different in kind is considered unexpected results. It is noted that it is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and

be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

Applicants allege that the adverse effects of racemic venlafaxine are reduced or avoided by using the optically pure derivatives of (-)-venlafaxine, and that compositions containing the (-)-venlafaxine can exhibit longer half-lives compared to racemic venlafaxine (see page 3, lines 26-30 of the instant specification). However, Applicant's assertions do not take the place of evidence of the record. Applicant's statements are mere conjecture without a showing of evidence. A showing of unexpected results must be based on evidence, not argument or speculation. *In re Mayne*, 104 F.3d 1339, 1343-44, 41 USPQ2d 1451, 1455-56 (Fed. Cir. 1997).

The Applicant's further argue that one of ordinary skill in the art would not have a reasonable expectation of success to predict that one enantiomer would have better pharmaceutical properties than the racemate itself. The Examiner respectfully disagrees. It is well known that, generally, one optical active component of a racemate is by far the more active if not the exclusively active isomer. Thus, it is expected that one or another optical isomer will exhibit a greater or lesser physiological effect, and thus better pharmaceutical properties.

The Applicant further emphasizes that a reasonable expectation of success is based on the question if one of ordinary skill in the art would have reasonably expected the claimed optical isomer would be pharmaceutically more advantageous. It is respectfully submitted that an optical isomer with a greater physiological effect is pharmaceutically more advantageous than the optical isomer with a lesser effect. As

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stated above, it is expected that one optical isomer will have a greater physiological effect than another.

Thus, for these reasons, Applicant's arguments are found unpersuasive. Said rejection is maintained.

Conclusion

All claims have been rejected; no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/JENNIFER M KIM/

Primary Examiner, Art Unit 1617

/Jody L. Karol/

Examiner, Art Unit 1617